UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,175	10/31/2003	John R. Bianchi	MSDI-434/PC316.08	1020

52196 7590 01/15/2009

KRIEG DEVAULT LLP
ONE INDIANA SQUARE, SUITE 2800
INDIANAPOLIS, IN 46204-2709

EXAMINER	
GHERBI, SUZETTE JAIME J	

ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
01/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/699,175	BIANCHI ET AL.	
	Examiner	Art Unit	
	SUZETTE J. GHERBI	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *362-425* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *362-385 and 391-425* is/are rejected.

7)☒ Claim(s) *386-390* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims **362-366, 368-369, 374-375, 377-382, 405-406, 408-410, 418-423, 425** are rejected under 35 U.S.C. 103(a) as being unpatentable over Pafford et al. 6,371,988. Pafford et al. discloses the invention as currently claimed noting figures 35-36 and 38-41 comprising:

An interbody fusion spacer for engagement within an intervertebral space between adjacent vertebrae, comprising: a spacer body (i.e 201) formed of bone 6:40-48 and defining a spacer height, a spacer width and a spacer length extending along a longitudinal axis, said spacer body including an insertion end (the opposite of ends 171 and 191) and an opposite tool engagement end (171, 191) each arranged along said longitudinal axis, said spacer body including upper and lower vertebral engaging

surfaces that are flattened (see i.e. figure 29 and 11:32-41 for flattened sides) from said insertion end to said tool engagement end to define said spacer height, said vertebral engaging surfaces including surface features (see figures 38-41) defined along said spacer length and structured to facilitate engagement with the adjacent vertebrae to inhibit movement of said spacer body within the intervertebral space, said spacer body defining a chamber 130 extending there through and opening onto said vertebral engaging surfaces; wherein said surface features comprise teeth 205. However Pafford et al. does not specify the shape of the teeth in embodiment of figure 40. Pafford et al. does however describe the machine shaping of teeth for a different embodiment see figure 8 that have a flat crest surface extending between a leading flank surface and a trailing flank surface (see elements 43-46 of figure 8 and 7:57-67, 8:1-5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the shaping described in figure. 8 on the teeth described in figure 40 because they perform the same functions which are to prevent backing out of the implant and because both embodiments are made from the same material and is deemed a design modification.

Pafford et al. also does not specify the use of a plurality of grooves inscribed into the spacer body as stated in claim 36. Pafford et al. does however disclose that the engaging surface are machined to facilitate engagement within the endplates of the vertebrae to prevent slippage in the form of a waffle design and states that any other suitable pattern may be utilized (see 13:1-17) and the grooves are therefore deemed a design modification.

Pafford et al. does not specifically state that insertion end and the opposite tool engagement end each comprising a flattened end surface. Pafford et al. does provided a flat insertion end. It would be obvious to one having ordinary skill in the art to provide a flattened portion on the tool engagement end such as a flattened edge in figures 40-41 in order to facilitate easier handling of the device during insertion.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 362, 368-385, 391-404 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-40 of U.S. Patent No. 6,409,765 in view of Patent 6,033438 claims 2-24. Patent '765 claims: (claim 1) A graft consisting essentially of cortical bone and comprising an elongated body having an outer surface and a longitudinal axis along a length of said body, said outer surface including a channel having a substantially convex surface and extending along a second axis substantially perpendicular to said longitudinal axis; (claim 6): The graft of claim 1 wherein the outer surface comprises upper and lower flattened portions; (claim 8): See patent claims 9-11 for all materials; wherein the vertebrae engaging surfaces comprise ribs, grooves or threads; (claim 28): wherein at least one of the insertion end and the tool engaging end include a chamfered portion. However, patent 6,409,765 does not claim a tool engagement with a slot. Patent 6,033,438 claims a tool engagement with a slot surrounding the tool engaging hole. It is obvious to one having ordinary skill in the art that while the current application claims are worded in a varied manner that the current patents would be

used to reject the current application because all of the features currently claimed are present throughout the claims of '765 and 438.

Allowable Subject Matter

.

Claims 386-390 are objected to as being dependent upon a rejected base claim (385, which is rejected under Double Patenting) but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J-J Gherbi whose work schedule is Maxi-Flex off every other Friday and whose telephone number is 571-272-4751.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suzette J Gherbi/
Primary Examiner, Art Unit 3738
13 January 2009